

FDA Commissioner's Fellowship Program
Class of 2015

FDA Commissioner's Fellowship Program

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Modernize Toxicology to Enhance Product Safety (2)

Alex M. Bailey, Tina Morrison, Brian Pullin (Fellow: Ryan Ortega)
Frederick A. Beland and Igor P. Pogribny (Fellow: Mekonnen Lemma Dechassa)

Stimulate Innovation in Clinical Trials and Personalized Medicine to Improve Product Development and Patient Outcomes (2)

Dionna J. Green (Fellow: Janelle Baker)
Michael A. Pacanowski (Fellow: Oluseyi Adeniyi)

Support New Approaches to Improve Product Manufacturing and Quality (3)

Eric A.E. Garber (Fellow: Ronnie O. Pedersen)
Denise Gavin (Fellow: Kimberly Shultz)
Anil K. Patri (Fellow: Sureshbabu Dadiboyena)

Ensure FDA Readiness to Evaluate Innovative Emerging Technologies (5)

Jonathan R. Deeds (Fellow: Amanda Windsor)
Stephanie L. Healey (Fellow: Clarence Rolle)
Yuan Hu (Fellow: Yan Zheng)
Aric D. Kaiser (Fellow: John Jameson)
Irshad M. Sulaiman (Fellow: Ying-Hsin Hsieh)

Implement a New Prevention-Focused Food Safety System to Protect Public Health (3)

Aref El-Demerdash and Fenhong Song (Fellow: Flavia Morales-Garcia)
Steven Foley (Fellow: Bijay Khajanchi)
James M. Hungerford (Fellow: Li Yang)

Facilitate Development of Medical Countermeasures to Protect National Health and Security (3)

Jane Bai (Fellow: Chia –Wen (Amy) Hsu)
Allison Kumar (Fellow: Lakshmi Kannan)
Keith Peden (Fellow : Stella Lee)

FDA Commissioner's Fellowship Program

2015 Preceptors and Fellows by Center

CBER Preceptors

Jane Bai
Alex Bailey
Keith Peden
Denise Gavin

Fellows

Chia-Wen Hsu
Ryan Ortega
Stella Lee
Kimberly Schultz

CDER Preceptors

Dionna Green
Michael Pacanowski

Fellows

Janelle Baker
Adeniyi Oluseyi

CDRH Preceptor

Aric Kaiser
Allison Kumar

Fellow

John Jameson
Lakshmi Kannan

CFSAN Preceptors

Jonathan Deeds

Fellow

Amanda Windsor

NCTR Preceptors

Frederick Beland
Steven Foley
Anil Patri
Igor Pogribny

Fellows

Mekonnen Lemma Dechassa
Bijay Khajanchi
Sureshbabu Dadiboyena
Mekonnen Lemma Dechassa

ORA Preceptors

Aref El-Demerdash
Stephane Healey
Yuan Hu
James Hungerford
Irshad Sulaiman

Fellows

Flavia Morales-Garcia
Clarence Rolle
Yan Zheng
Li Yang
Ying-Hsin Hsieh

FDA Commissioner's Fellowship Program

2015 Fellows



Oluseyi Adeniyi, Ph.D.

Center for Drug Evaluation and Research

Preceptor: Michael Pacanowski

Scientific & Professional Background

2015 Ph.D. Pharmaceutical Sciences, University of Michigan

2009 Pharm.D. University of Michigan

Research Interests

Prior to joining the FDA, practiced as a pharmacist and conducted research. My research interests have centered on improving drug delivery by circumventing cellular and subcellular barriers. Mainly, I studied how a protein vaccine adjuvant can be manipulated for cell-specific targeting while enhancing immune response to vaccine antigen and I also studied strategies to enhance gene delivery. My current efforts at the FDA are directed at finding opportunities for targeted therapies in clinical drug development, particularly for common chronic diseases.

CFP Project Summary

Project Title: *Identifying opportunities for personalization in the drug development pipeline*

Regulatory Science Priority Area: [Stimulate Innovation in Clinical Trials and Personalized Medicine to Improve Product Development and Patient Outcomes](#)

The goal of the proposed research is to systematically characterize liabilities and opportunities for biomarker-based development in the pharmaceutical pipeline. Specifically, for a cross-section of drugs being developed for critical unmet medical/public health needs that have progressed through Phase 1 trials, we will systematically review key elements of the overall program to identify (1) the presence of pharmacogenomic liabilities (e.g., racial/ethnic effects, high pharmacokinetic variability/outliers, disease or drug target gene variants), and (2) whether liabilities are being managed through prospective biomarker assessments or targeted drug development. Impact: The proposed research will impact drug development and regulatory review processes by (1) improving FDA guidance to sponsors who are developing drugs for specific diseases or drug mechanisms, (2) identifying best practices for translating exploratory biomarker research to personalized medicines, (3) prioritizing allocation of limited resources to areas where biomarker development investments will be productive, and (4) enhancing operational aspects of FDA's investigational drug review enterprise.



Janelle Baker, M.D.

Center for Drug Evaluation and Research

Office of Clinical Pharmacology

Preceptor: Dionna Green, M.D.

Scientific and Professional Background

2014-2015 General Pediatrician
2011-2014 Pediatric Residency-State University of New York-Children's Hospital of Buffalo
2007-2011 Medical Doctorate-Ross University School of Medicine
2001-2005 Bachelors of Science in Biology, University of Texas-Arlington

Research Interests

Dr. Baker's interests are in neonatal and pediatric clinical trials and drug development. She is a general pediatrician who has had many years of experience in clinical research. Her previous research projects have primarily focused on clinical decision-making and juvenile idiopathic arthritis.

CFP Project Summary

Project Title: *Clinical Trial Simulation as a Means to Improve Pediatric and Neonatal Drug Development Trials*

FDA Regulatory Science Priority Area: [Stimulate Innovation in Clinical Trials and Personalized Medicine](#)

The purpose of this regulatory research project is to identify failed pediatric and neonatal clinical trials, assess the reasoning for trial failure, and conduct simulation experiments to explore adjustments in trial methodology that could have enabled trial success. Clinical trial simulation will provide a means for demonstrating previously failed pediatric development programs that could have been successful with specific adjustments to trial methodology. By successfully employing simulation to select trials, this research has the potential to positively impact public health and the ability to design a trial that has the greatest likelihood of success for neonatal and pediatric drug development studies.



Sureshbabu Dadiboyena, Ph.D.

National Center for Toxicological Research

Division of Nanotechnology (NCTR-ORA)

Preceptor: Anil K. Patri, Ph.D.

Scientific & Professional Background

2012-2015	Henry M. Jackson Fellow, National Institutes of Health (NIMH), Bethesda, MD
2010-2012	Post-doctoral Associate, Torrey Pines Institute, Port St. Lucie, FL
2008-2009	Post-doctoral Fellow, Reviva Pharmaceuticals, San Jose, CA
2010-2014	Diploma in Intellectual Property, WIPO-UNISA, Geneva
2003-2008	PhD, Synthetic Organic Chemistry, Jackson State University, Jackson, MS

Research Interests:

Suresh's previous research was in the areas of: (a) Total Synthesis and Methodology of Natural Products, Bioactive Heterocycles and Peptides, (b) Development of Novel PET radioligands for Imaging tau-protein aggregates, and (c) CNS Drug-Discovery therapeutics, and combinatorial chemistry.

CFP Project Summary

Project Title: *Synthesis, Surface functionalization, Quantification of coatings and their influence on Biological properties of Nanomaterials*

FDA Regulatory Science Priority Area: [Support New Approaches to Improve Product Manufacturing and Quality](#)

Nanoparticle-based therapeutic agents contain passivating surface coatings to minimize immune system recognition thereby prolonging their blood half-life and enhanced accumulation in tumor tissue by enhanced permeation and retention (EPR) effect. It is known that lack of this passivating coating will lead to immediate opsonization, macrophage uptake and liver and spleen distribution, minimizing the therapeutic efficacy of nanomedicines. The molecular weight, density, stability, hydrophobicity and uniformity of coatings dictate the product safety, biodistribution and efficacy. These critical attributes should be monitored for product quality and consistency to assure reproducible and predictable safety, bio-distribution, and efficacy in clinical trials and beyond. The scientific rationale of this project is to contribute to FDA's scientific understanding of the nanoparticles by: (a) Synthesizing nanoparticles with variable degree of surface coatings similar to those used in nanomedicines in current products in clinical trials, (b) Quantitative assessment of the stability of coatings through HPLC, TGA, Quartz-crystal microbalance (QCM), and separation through Field Flow Fractionation techniques, (c) conduct in vitro biocompatibility and in vivo pharmacokinetic studies of nanoparticles with variable degree of coatings to relate how coatings might effect safety and effectiveness. The regulatory objective of this research project is to develop standards for these test methods to assist in regulatory review of emerging technologies.



Chia-Wen (Amy) Hsu, Ph.D.

Center for Drug Evaluation and Research (CDER)

Office of Clinical Pharmacology (OCP)

Division of Applied Regulatory Sciences (DARS)

Preceptor: Jane Bai

Preceptor: Jane Bai, Ph.D.

Scientific & Professional Background

2012-2015 Postdoctoral Research Fellow, National Center for Advancing Translational Sciences (NCATS), National Institutes of Health (NIH)

2012 Ph.D., Pharmaceutical Sciences
University of North Carolina at Chapel Hill

2006 B.S., Chemistry
National Taiwan University

Research Interests

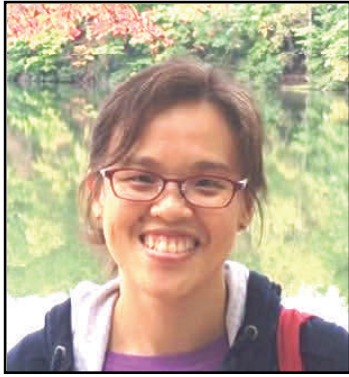
Amy is interested in drug repurposing and safety assessment using her systems pharmacology and systems toxicology expertise. As a postdoctoral fellow at the NIH/NCATS, Amy worked with the U.S. Toxicology in the 21st Century (Tox21) program, where she utilized *in vitro* assays, quantitative high-throughput screening (qHTS), and informatics approaches to rapidly and efficiently test ~10K environmental chemicals and drugs for their ability to cause potential adverse effects on humans or be used for oncology drug development and for the compounds' mechanism of action (MOA). In graduate school, Amy developed novel technologies such as live cell biosensors and optogenetic tools to enable quantitative imaging and analysis of signaling networks in living cells.

CFP Project Summary

Project Title: *Development of medical countermeasures for treating Ebola virus disease*

FDA Regulatory Science Priority Area: [Facilitate Development of Medical Countermeasures to Protect National Health and Security](#)

Ebola virus disease (EVD) caused nearly 28,000 deaths mainly in West Africa with some sporadic cases in the U.S. and Europe in the recent outbreak. EVD remains to be a significant threat to global public health due to lack of approved anti-Ebola medical countermeasures (MCMs). To date over 100 approved drugs, including FDA-regulated products with established safety and pharmacokinetic profiles and commercial availability, have been shown to suppress Ebola infectivity *in vitro* and *in vivo*. However, most drugs might not be effective against EVD at their already approved doses and their anti-EVD mechanisms of action (MOAs) remain unclear. Therefore, the objective of the proposed project is to identify efficacious and safe anti-Ebola MCMs based on potent drug pairs with complementary MOAs and optimal pharmacokinetic and safety profiles. The anti-Ebola MCMs and results obtained from this study will help the FDA prevent and control future EVD epidemic.



Ying-Hsin Hsieh, Ph.D.

Microbiological Sciences Branch

Southeast Regional Laboratory

Office of Regulatory Affairs

Preceptor: Irshad M. Sulaiman, MSc, MPhil, Ph.D.

Scientific & Professional Background

2000 B.S. Nutrition Science, Taipei Medical University

2002 M.S. Molecular and Cellular Biology, Taipei Medical University

2007 M.S. Molecular Genetics and Biochemistry, Georgia State University

2011 Ph.D. Microbiology, Georgia State University

2012-2015 Research Scientist, Georgia State University

Research Interests

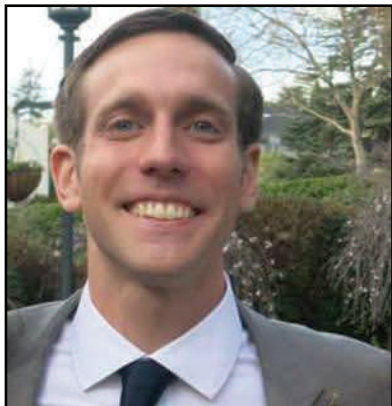
Dr. Hsieh's general research interest is on the biology of bacterial pathogens and how they relate to the human diseases. Although most bacterial infections can be reduced by either vaccination or antibiotic treatment, there are still some new identified bacterial pathogens and some old bacterium with new forms of virulence due to resistance of antibiotics without the cure. Thus, to establish rapid and accurate diagnostic methods and to develop the potential therapies would be the key for the public health surveillance.

CFP Project Summary

Project Title: *Rapid Diagnostic Method Development for the Detection and Differentiation of Campylobacter*

FDA Regulatory Science Priority Area: [Ensure FDA Readiness to Evaluate Innovative Emerging Technologies](#)

Description: *Campylobacter* is a Gram-negative bacterium and is the main cause of diarrhea in US and worldwide due to the consumption of uncooked food. This type of bacteria is highly contagious and harmful to children, elders, and immunocompromised people who have a weakened immune system. The damage can be ranged from mild to severe depending on the strains. Several species including *C. jejuni* and *C. coli* have been identified for causing human pathogenic diseases. Thus, isolation, identification, and the classification of *Campylobacter* from food, outbreak or other sources would be a key for the infection surveillance. In addition, using multi-locus sequence typing (MLST) and the whole genome sequencing approach would further provide precise evaluation on the strains and the details of strains characteristics. These tools are the key for conducting surveillance studies and for the treatment development of public health importance.



John Jameson, Ph.D.

Multi-Center Fellowship in Regenerative Medicine

Center for Devices and Radiological Health (CDRH)

Center for Biologics Evaluation and Research (CBER)

Primary Preceptor: Aric Kaiser, M.S. (CDRH)

Scientific & Professional Background

2014-2015	Research Fellow, Mayo Clinic, Rochester, MN
2014	Ph.D. Biomedical Engineering, Marquette University, Milwaukee, WI
2012-2014	Advanced Light Source (ALS) Doctoral Fellow in Residence, Lawrence Berkeley National Laboratory, Berkeley, CA
2007	B.S. Biomedical Engineering, University of Virginia, Charlottesville, VA

Research Interests

John's research interests are in characterization and mechanical testing of biomaterials and human tissues. His graduate research focused on examining relationships between the mineralization, porosity, and mechanical properties of healthy and diseased human bone. As part of this work, he served as an investigator on the X-ray tomography, X-ray scattering, and infrared end stations at the ALS particle accelerator in Berkeley, CA. During his post-doctoral training at the Mayo Clinic, he developed computational modeling techniques to simulate X-ray phase contrast imaging of soft tissues for cardiovascular applications.

CFP Project Summary

Project Title: *Ensuring FDA readiness to regulate modern bone void filler devices: an investigation of regenerative terms used in premarket notifications and scientific literature*

FDA Scientific Priority Area: [Ensure FDA Readiness to Evaluate Innovate Emerging Technologies](#)

The goal of regenerative medicine products is to restore bodily function through replacement or regeneration of human cells, tissues, or organs. Recent advances in biomaterials processing techniques have enabled modifications to the physical properties of these products, which have subsequently been tied to enhanced regenerative capabilities after implantation. In orthopaedics, these practices are becoming increasingly apparent in regulatory submissions involving bone void filler devices, which are intended to fill skeletal voids in the extremities, spine, and pelvis. The purpose of this project is to: 1.) provide a better understanding of regenerative terms used in bone void filler device submissions and in the scientific literature, and 2.) develop practical tools that facilitate transparency and contribute to a more efficient review process for future bone void filler devices.



Lakshmi Kannan, Ph.D.

Emergency Preparedness/ Operations and Medical Countermeasures Program (EMCM)
Office of Center Director, Center for Devices and Radiological Health (CDRH)

Preceptor: Allison Kumar, Ph.D.

Scientific & Professional Background:

Education:

2009: PhD, Cell & Molecular Biology, University of Arkansas

2004: M.S., Biotechnology, University of Madras

2002: B.S., Chemistry, University of Madras

Experience:

2014-15: Instructor in Medicine, Harvard Medical School/BIDMC

2009-14: Postdoctoral Research Fellow, Harvard Medical School/BIDMC

2005-09: Senior Graduate Research Assistant, University of Arkansas

Research Interests:

Dr. Lakshmi Kannan's current research and development interests span across Acute Trauma and Critical Care, Traumatic Brain Injury, Ischemia, Biomarkers and Physiological Monitoring, and Regulatory Strategy. As an instructor at Harvard Medical School and during her postdoctoral research work, Dr. Kannan extensively studied trauma and tissue injury to identify novel biomarkers for the diagnosis of diseases and therapeutic agents, with special focus on ischemia/reperfusion injury.

CFP Project Summary:

Project Title: *Advancing the development of endpoints in TBI: Scientific, Clinical, Patient and Regulatory Considerations*

FDA Regulatory Science Priority Area: [Facilitate Development of Medical Countermeasures to Protect National Health and Security](#)

Project Description: Traumatic Brain Injury (TBI) is a major medical problem. Each year in the United States, about 2 million people suffer TBI; it is a contributing factor in a third of all injury-related US deaths. In the military, TBI is one of the most common causes of injury and disability in active duty service members. Researchers have been actively working on better ways to diagnose and treat TBI, but at present, we have no "cures" for TBI, or even very good ways to diagnose if it has happened, or its severity. As such, FDA has not approved any therapeutic drug, medical device or diagnostic tool for patients suffering from mild and moderate TBIs. My FDA Commissioner's Fellow research project focuses on the development of a cross-Center and cross-Agency team of subject matter experts that would help facilitate an approach for adoption of brain disease-specific open data standards in order to improve the quality, efficiency and cost-effectiveness of TBI clinical trials. Aligning with the TED (Traumatic Brain Injury Endpoints Development) initiative, which is funded through Congressionally Directed Medical Research Program, I am working towards developing scientific and consensus-driven endpoints that can be used in the clinical trials needed to support approval of products in TBI diagnosis and treatment.



Bijay Khajanchi, Ph.D.

Division of Microbiology
National Center for Toxicological Research (NCTR)
Jefferson, AR 72079

Preceptor: Steven Foley, Ph.D.

Scientific & Professional Background:

Institution	Degree	Year	Field
University of Dhaka, Bangladesh	B.Sc.	2000	Microbiology
University of Dhaka, Bangladesh	M.Sc.	2002	Microbiology
University of Texas at Galveston	Ph.D.	2011	Microbiology & Immunology
University of Texas at Houston	Postdoc	2011-2015	Molecular Biology

Research Interests:

My research interest is to investigate the role of different signaling systems in regulating gene expression and virulence mechanisms of Gram-negative bacteria particular interest in to the food- borne pathogens using cutting-edge molecular techniques. I am specifically interested to understand the detail underlining mechanisms as to how plasmid encoded virulence determinants and antibiotic resistance factors spread among bacterial pathogens isolated from food sources, animals and humans. In the long term, I would like to discover new molecular tools to rapidly and efficiently identify emerging foodborne pathogens as well as I am interested to develop novel strategies to control spread of the plasmid encoded virulence and antibiotic resistant factors that allow bacterial pathogens to increase their ability to causes severe public health problem.

CFP Project Summary:

Project Title: *Evaluation of incompatibility group IncFIB plasmid-mediated virulence in Salmonella enterica*

FDA Regulatory Science Priority Area: [Priority area 6: Advancing Regulatory Science at FDA strategic plan, to "Implement a New Prevention-Focused Food Safety System to Protect Public Health"](#)

Salmonellosis, the second leading cause of bacterial foodborne illness in the United States, is mainly associated with the consumption of foods contaminated with *Salmonella*. In the US, *Salmonella* infections lead to ~20,000 hospitalization and ~400 deaths annually. In current study, I am investigating the role incompatibility group IncFIB plasmid-encoded factors, such as iron acquisition component(s) in regulating virulence of *Salmonella enterica*. The long term goal of this study is to understand how plasmid encoded factors influence virulence and horizontal gene transmission among *Salmonella* and related species, which may be beneficial to develop novel strategies to control the spread of virulence and antimicrobial plasmids among foodborne pathogens. The outcomes of this research may aid FDA scientists by informing regulatory decisions associated with the use of antimicrobial agents in food animal production and improve human food safety guidelines.



Stella Lee, Ph.D.

Center for Biologics Evaluation and Research (CBER)

Preceptor: Keith Peden, Ph.D. (CBER)

Scientific & Professional Background

- | | |
|-----------|---|
| 2015-2015 | Postdoctoral Fellow, Department of Molecular Biology and Genetics, Johns Hopkins University School of Medicine, Baltimore, MD |
| 2009-2015 | Ph.D. Human Genetics and Molecular Biology, Johns Hopkins University School of Medicine, Baltimore, MD |
| 2006-2009 | M.S. Carver College of Medicine, University of Iowa, Iowa City, IA |
| 2002-2006 | B.S. Ewha Womans University, Seoul, South Korea |

Research Interests

Stella has been interested in solving fundamental scientific questions that have significant clinical relevance. Previously, she pioneered a project to understand the regulation of telomere length. Dysregulated telomere length affects many cancer and age-related disorders; thus, understanding the mechanism of telomere length regulation is critical. She developed a new mammalian assay that allows visualization of telomere elongation at a single telomere in just one cell cycle. Using this assay, she discovered novel regulators of telomere elongation.

CFP Project Summary

Project title: *Development of a common platform to assess neutralizing antibodies for pathogenic human viruses*

FDA Regulatory Science Priority Area: [Facilitate Development of Medical Countermeasures to Protect National Health and Security](#)

Determination of vaccine effectiveness is frequently done by measuring the presence of neutralizing antibodies. A major problem with measuring neutralizing antibodies against highly pathogenic viruses, e.g., Ebola virus, is that such studies need to be carried out in high-containment level laboratories, which are very limited in availability and expensive to operate. The overall goal of this project is to develop a high-throughput platform technology to assess neutralizing antibodies for various pathogenic viruses that can be performed under standard laboratory conditions. This platform will accelerate the evaluation of vaccine candidates and aid in new vaccine development, contributing to the public-health response to emerging lethal pathogenic viruses.



Mekonnen Lemma Dechassa, D.V.M., Ph.D.

National Center for Toxicological Research (NCTR)

Division of Biochemical Toxicology

Preceptors: Dr. Igor Pogribny and

Dr. Fredrick Beland

Education

1990 - 1996	D.V.M., Addis Ababa University, Ethiopia
1999 - 2001	M.Sc. in Molecular Biology, Katholieke Universitet Leuven, Belgium
2003 - 2008	Ph.D., Molecular Biology, Microbiology and Biochemistry, Southern Illinois University Carbondale

Professional Experience

1996 - 1999	Lecturer at Addis Ababa University, Ethiopia
2009 - 2010	Postdoctoral Fellow at Colorado State University
2010 - 2012	American Heart Association Postdoctoral Fellow, Grant 10POST4190042, Colorado State University
2012 - 2015	HHMI Postdoctoral Fellow, Colorado State University

Research interest:

The focus of my graduate and postdoctoral research experience includes biochemical and biophysical characterization of proteins, protein-protein/protein-DNA interactions, mechanism of ATP-dependent chromatin remodeling and chromatin structural analysis. Currently, I am interested to understand how chromatin structure and epigenetic marks are related to disease development. I am interested to investigate how various signals induce changes in chromatin accessibility and alter gene expression that lead to disease initiation and progression, and use such information in identifying new drug targets and biomarkers for early disease detection as well as for assessing drug safety.

CFP Project Summary:

Project Title: *Chromatin structural state dynamics during NAFLD associated liver carcinogenesis*

FDA Regulatory Science Priority Area: **Modernize Toxicology to Enhance Product Safety**

Nonalcoholic fatty liver disease (NAFLD) is one of the risk factors for hepatocellular carcinoma (HCC). The molecular mechanisms of NAFLD-associated HCC are not well known and, early detection and treatment options are limited. This project involves the analysis of chromatin structure, histone epigenetic marks, and gene expression profiles at different stages of the NAFLD-HCC using a relevant mouse model. The differential chromatin structural states associated with the disease development and progression will be analyzed and correlated with epigenetic marks and gene expression patterns to identify regulatory DNA elements that are associated with differentially expressed genes in NAFLD-HCC. The findings from the proposed study will be part of an effort toward understanding the molecular mechanism of NAFLD-HCC development, which is critical in identifying new targets for the diagnosis and treatment of the disease.



Flavia Morales-García, Ph.D.

Office of Regulatory Affairs (ORA)

Preceptors: Fenhong Song, Ph.D. and Aref El-Demerdash, Ph.D.

Scientific & Professional Background

2015 Postdoctoral Research Associate, University of Puerto Rico

2014-2015 Assistant Professor, University of Puerto Rico in Humacao

2014 Ph.D., Analytical Chemistry, University of Puerto Rico

1999 B.S., Chemistry, University of Puerto Rico, Río Piedras Campus

Research Interests

Dr. Morales-García's research background lies in developing methods for quantifying atmospheric aerosols in the Caribbean basin. Her graduate research focused on the physicochemical characterization and size-resolved analysis of atmospheric particles. She also has three years of experience in a regulated pharmaceutical industry, executing the analytical method transfer of final products, as well as performing analytical testing of finished products as part of validation and stability studies. Her current research interest is in developing mass spectrometry-based methods to detect active pharmaceutical ingredients in dietary supplements and to characterize drug substances.

CFP Project Summary

Project Title: *Method development for the screening and quantification of undeclared drugs in dietary supplements using ultra-high performance liquid chromatography-quadrupole-orbitrap mass spectrometry*

FDA Regulatory Science Priority Area: [Implement a New Prevention-Focused Food Safety System to Protect Public Health](#)

The scientific community has reported that an alarming number of dietary supplements are adulterated with active pharmaceutical ingredients (APIs), such as steroids, statins, growth hormones, and pain killers; medications for erectile dysfunction, weight loss, and hair loss; and other regulated drugs. These adulterated supplements are illegal and represent a serious health risk for members of the public who consume the dietary supplements without knowing about the presence of the adulterating drugs. To address this problem, this project aims to use state-of-the-art high resolution mass spectrometry techniques to determine the presence and quantity of APIs in dietary supplements and thus advance the FDA mission of protecting the public health.



Ryan Ortega, Ph.D.

Multi-center Fellowship in Regenerative Medicine

Center for Biologics Evaluation and Research
(CBER)

Center for Devices and Radiological Health (CDRH)

Preceptors: Alex Bailey (CBER), Tina Morrison
CDRH), Brian Pullin (CDRH)

Scientific & Professional Background

2014 – PhD in Biomedical Engineering, Vanderbilt University

2012 – Teaching Affiliate, Vanderbilt Center for Teaching

2010 – M.S. in Biomedical Engineering, Vanderbilt University

2008-2014 – Provost Fellow, Vanderbilt University

2008 – B.E. in Biomedical Engineering, Vanderbilt University

Research Interests

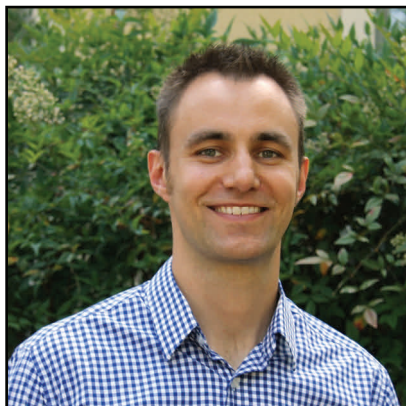
My current research interests include computational and mathematical modeling for regenerative medicine, and regulatory issues surrounding this area. Previous research projects included developing a novel mathematical model of the magnetic properties of iron oxide nanoparticles as well as discovery phase research with a macrophage targeting, siRNA delivering nanoparticle for immunological engineering.

CFP Project Summary

Project Title: *Enhancing Regulatory Review of Computational and Mathematical Modeling for Regenerative Medicine Products*

FDA Regulatory Science Priority Area: [Modernize Toxicology to Enhance Product Safety](#)

Due to the innovative nature and complexity of regenerative medicine (RM) products, the ability of traditional pharmacology/toxicology (P/T) testing strategies and available animal models to identify and characterize safety and bioactivity profiles is often limited. Computational and mathematical modeling and simulation (CMMS) are being used to support development of RM products at the discovery phase, and are increasingly more important for later phase product development. The use of CMMS techniques to support the use of RM products has the potential to complement and/or replace certain animal testing strategies and *in vitro* tests through the rapid and cost-effective evaluation of multiple parameters and/or experimental systems. While some product areas have a robust history of utilizing CMMS in regulatory submissions, the use of CMMS in the translational development of RM products has been limited to-date. Therefore, in order to inform P/T reviewers in CBER/OCTGT about the possible applications of CMMS that exist and to provide them with tools to facilitate review of submissions that contain some CMMS component, I will survey the modeling expertise that currently exists within CBER and other FDA Centers then translate and organize that expertise into a set of best practices and considerations (e.g., job-aid or Standard Operating Procedure [SOP]) for reviewing CMMS specifically for regenerative medicine.



Ronnie O. Pedersen, Ph.D.

Center for Food Safety and Applied Nutrition
Division of Bioanalytical Chemistry

Preceptor: Eric A. E. Garber, Ph.D.

Scientific & Professional Background

2014–2015 Chemist, Analytical Support, Novo Nordisk, Denmark
2009–2014 PhD, Chemistry, Duke University, USA
2008–2009 MSc, Nanoscience, Aarhus University, Denmark

Research Interests

Applying LEAN thinking to analytical method development within scientific and regulatory context. This follows from my work as a graduate student where I researched self-assembled DNA nanostructures. The project included development of a nanoscale scaffolding platform for cell receptor stimulation, which has potential applications in tissue engineering and wound healing. Developing this required the use and optimization of a wide range of analytical methods such as bioassays, ELISA, PAGE and microscopy. At Novo Nordisk, I further pursued this interest, working primarily with ELISA and FTIR within both GLP and cGMP LEAN environments.

CFP Project Summary

Project Title: *Performance Evaluation of a Multiallergen Immuno Assay in Botanical Dietary Supplements and Spices*

FDA Regulatory Science Priority Area: [Support New Approaches to Improve Product Manufacturing and Quality](#)

The aim of my research project is to evaluate and optimize the performance of a newly developed multiplex immunoassay with botanical dietary supplements and spices. FDA enforcement of the Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) relies on confirmation between two single-analyte ELISAs. Such assays require two days to complete for a single allergen at a cost exceeding \$ 1,200. As a result, enforcement of FALCPA using current methods is exceedingly expensive. The newly developed multiallergen immunoassay simultaneously detects gluten and 14 different food allergens using multiple antibodies, cutting the time and cost of analysis by more than an order of magnitude. My project is part of the extensive evaluation and validation needed for the FDA to formally adopt this assay.



Clarence J. Rolle, Ph.D.

Office of Regulatory Affairs (ORA)

Preceptor: Stephanie Healey:

Scientific & Professional Background

2012 - 2015 Postdoctoral Fellow, Johns Hopkins University, Baltimore, MD
2011 Ph.D. in Chemistry, Georgia Institute of Technology, Atlanta, GA
2005 B.S. in Chemistry, Hobart and William Smith Colleges, Geneva, NY

Research Interests

Dr. Rolle is an inorganic chemist with extensive research experience in the synthesis and characterization of small molecules. In his work, he has investigated the development of environmentally benign transition metal catalysts, as solutions to outstanding problems in bench-top organic synthesis, commodity chemical production and energy storage. Currently, he is interested in reducing the impact that anthropogenic sources of chemicals have on human health and the environment.

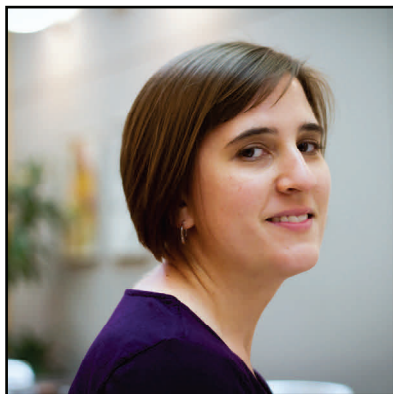
CFP Project Summary

Project Title: *Method development in the detection of radioactive contamination of food products*

FDA Regulatory Science Priority Area: [Ensure FDA Readiness to Evaluate Innovative Emerging Technologies](#)

Commissioner's Fellowship Project Overview

The FDA faces increasing challenges in ensuring the safety of the nation's food supply from radioactive contamination. It is imperative that the agency is capable of rapidly detecting gamma-radiation in foods, due to the possibility of contamination from either nuclear accidents or terrorism. Gamma-ray spectroscopy is a powerful and informative tool used to identify radioactive material and has previously been successfully implemented at WEAC to detect contamination in foods. However, current methods are limited because calibrations must be made before samples can be measured. These calibrations are time consuming, requiring certified gamma radiation sources that match the geometry and matrix of the food sample in question. To overcome these issues, a number of software and modeling techniques, which are capable of simulating a variety of sample geometries and compositions, will be examined as alternative method for calibration. Implementing this technology would improve the laboratory's capabilities to quickly detect contamination and protect the public.



Kimberly Schultz, Ph.D.

Center for Biologics Evaluation and Research (CBER)

Preceptor: Denise Gavin, Ph.D.

Scientific & Professional Background

- 2008-2015 Postdoctoral Fellow, Department of Molecular Microbiology and Immunology, Johns Hopkins Bloomberg School of Public Health
- 2002-2008 Ph.D. Cellular and Molecular Biology, University of Wisconsin – Madison
- 1998-2002 B.S. Biology, SUNY Geneseo

Research Interests (check past tense)

Kim's research has focused on virus-host interactions. Her graduate studies identified virus-activated cellular signaling pathways and integration points that determine cellular fate. Her postdoctoral studies investigated control of the immune response during viral infection of the Central Nervous System (CNS). She determined that transcription factor expression was associated with developmental-determinants of infection in cultured neurons. Additionally, she demonstrated that these transcription factors worked independently of one another to regulate the innate and adaptive immune responses and viral RNA clearance. She also used high-throughput analysis to identify unique antibody-mediated signaling pathways that may limit intracellular virus replication.

CFP Project Summary

Project Title: *Establishment of a database and meta-analysis of Chimeric Antigen Receptor T-cells targeting CD19 (CART19): Analysis of product characteristics and critical product attributes to guide chemistry, manufacturing, and control (CMC).*

FDA Regulatory Science Priority Area: [Support New Approaches to Improve Product Manufacturing and Quality](#)

Immunotherapies augment or modulate the patient's own immune system to treat their disease. T-cells, a component of our immune system, can be genetically engineered to target cells responsible for disease. Chimeric Antigen Receptor T-cell (CART) immunotherapy uses ex vivo genetically reprogramed T-cells to specifically target tumor cells for destruction following infusion. This therapy, which has potential as a treatment for cancers with unique cellular markers, has been most thoroughly investigated for cancers of white blood cells that express the cellular marker CD19, such as leukemia. CART19 therapy has led to complete remission in some patients for whom all other therapies have failed, but for others, it has led to life-threatening side effects. This therapy combines gene therapy with individualized medicine, creating a patient-specific product through a multi-step manufacturing procedure that raises scientific and technical issues that may impact product safety. The overarching goal of this project is to develop analytics that will support risk prediction to minimize severe adverse events. Upon analysis, the FDA will provide industry with recommendations describing how critical product attributes and process parameters are related to safe and effective CART19 therapies.



Amanda M. Windsor, Ph.D.

Center for Food Safety and Applied Nutrition
Division of Analytical Chemistry

Preceptor: Jonathan R. Deeds, Ph.D.

Scientific & Professional Background

2013-2015 Molecular Support Scientist, National Museum of Natural History

2012-2013 Endeavour Awards Postdoctoral Fellow, Australian Museum

2011-2012 Marine Invertebrate Barcode Technician, National Museum of Natural History

2004-2011 PhD., Environmental and Evolutionary Biology, University of Louisiana at Lafayette

1999-2003 B.S., Marine Science and Biology, Coastal Carolina University

Research Interests

Amanda is a Crustacean Biologist with a focus on taxonomy and biodiversity. Her primary interests involve utilizing a combination of molecular phylogenetics and traditional morphological descriptions to resolve long-standing taxonomic issues in brachyuran crabs. This approach has led Amanda and her colleagues to describe 2 new species, 3 genera, and revise a family of American decorator crabs. As a Commissioner's Fellow, Amanda will apply her training to resolve pressing taxonomic issues within commercially important crustaceans.

CFP Project Summary

Project Title: *Resolving Priority Taxonomic Issues in Commercial Swimming Crabs that Impact Seafood Labeling in the United States*

FDA Regulatory Science Priority Area: [Ensure FDA Readiness to Evaluate Innovative Emerging Technologies](#)

This project aims to address several key priority taxonomic issues that are currently affecting the proper regulation and labeling of crabmeat in support of the FDA's role in regulating seafood labeling standards. Specifically, the project will address currently unresolved taxonomic issues within two of the most widely traded crab species, *Callinectes sapidus* (blue crab) and "*Portunus haanii*" (red swimming crab) which will require a combination of morphological and molecular analyses of specimens collected from throughout their respective geographic ranges. The primary objectives are to 1) determine whether the southern subspecies of blue crab, *C. sapidus acutidens*, is morphologically and genetically distinct enough to warrant recognition as a distinct species; 2) determine exactly which species of crab is currently being harvested and sold as *Portunus haanii* to allow proper labeling of these products and management of this fishery; 3) generate sequences from voucher specimens obtained from fish markets and research collaborators from around the world to continue expansion of the FDA Reference Standard Sequence Library for seafood.



Li Yang, Ph.D., DABT,

Applied Technology Center, PRL-NW, ORA

Preceptor: James Hungerford, PhD

Scientific & Professional Background

Dr. Li Yang completed her PhD training with major of toxicology from University of Nebraska Medical Center in 2010. During her PhD training, she has conducted breast cancer case-control and cross-sectional studies, and prostate cancer case-control study with the goal of detecting early biomarkers of these diseases. By using ultra-performance liquid chromatography (UPLC) coupled with tandem triple quadrupole mass spectrometer (MS/MS), Dr. Yang found that there is significantly higher level of estrogen DNA adducts, which are biomarkers of DNA damage, in the blood/urine samples in cancer cases comparing with healthy controls. After completing these projects, Dr. Yang joined University of Pittsburgh School of Medicine as a fellow in 2010. From 2011 to 2014, Dr. Yang was awarded for a Department of Defense Breast cancer research program Postdoc fellowship. Dr. Yang has conducted cell study and animal model to test the hypothesis that sulforaphane, bioactive component extracted from broccoli, can modulate estrogen DNA oxidation pathway by up-regulating Nrf2-Keap1 pathway. Dr. Yang found that sulforaphane can be an antioxidant to prevent estrogen DNA damage, which indicates its potential as a chemoprevention agent in the clinical settings. In summary, Dr. Yang has accumulated experience in epidemiology, biostatistics, mass spectrometry, cell study, animal model, and cancer prevention strategies by using food based antioxidant.

Research Interests:

Developing fast screening methods to detect toxins in food and dietary supplements; developing mass spectrometry based methods to characterize these toxins or their metabolites; regulatory science.

CFP Project Summary

Project Title: *Development of screening methods for diarrhetic shellfish toxins and azaspiracid shellfish toxins using surface plasmon resonance and confirmation by LC-MS/MS for regulatory application in seafood*

FDA Regulatory Science Priority Area: [Field-usable detectors for microorganisms, chemical hazards, and economic adulterants](#)

Marine biotoxins, produced by microalgae, are small molecules accumulated in filter-feeding fish or shellfish. After consuming seafood contaminated with marine biotoxins, humans develop symptoms such as diarrhea, vomiting, paralysis and even death. These biotoxins are a public health concern and so monitoring is warranted. The goal of the study is to develop rapid field detection methods to quickly test diarrhetic shellfish toxins (DSTs), azaspiracid shellfish toxins (AZTs) and domoic acid (DA) in shellfish. Liquid chromatography coupled with mass spectrometry (LC-MS/MS) methods will be developed as regulatory confirmatory approaches. A Thermo triple quadrupole and a Q exactive mass spectrometer will be used. By conducting proposed study, food safety will be protected and public health will be promoted.



Yan Zheng, Ph.D.

Office of Regulatory Affairs, Northeast Region

Preceptor: Yuan Hu, M.D.

Scientific & Professional Background

2015(May-Oct)	Intern/Temp Project Associate II, Regeneron Pharmaceuticals, Inc.
2014	Postdoctoral Fellow, Department of Pathology, NYU Langone Medical Center
2013	Ph.D. Virology & Cell Biology, Albert Einstein College of Medicine
2007	B.S. Biological Sciences, Peking University, China

Research Interests

Yan is interested in the field of infectious diseases. Her graduate research analyzed the cellular entry and release mechanism of alphaviruses, which cause encephalitis or arthritis, for antiviral strategy. Her postdoctoral research isolated and analyzed patients' neutralizing antibodies for better HIV vaccine development.

CFP Project Summary

Project Title: *Development of foodborne virus concentration method and its application in viral pathogen detection from food matrix*

FDA Regulatory Science Priority Area: [Ensure FDA Readiness to Evaluate Innovative Emerging Technologies](#)

Hepatitis A virus (HAV) ranks fourth among identified causes of foodborne diseases. The presence of HAV is rarely confirmed through direct isolation from contaminated food samples, suggesting the need for a more efficient virus detection method. Current HAV detection procedure includes sample preparation such as virus concentration and RNA-extraction, as well as follow-up molecular amplification and analysis. At a low viral concentration, which is typical for food matrix, higher sample preparation efficiency leads an improved sensitivity of virus detection. My fellowship project will focus on optimizing the sample preparation method. Specifically, I will optimize current lab internal polystyrene carboxylate bead-based approach, and compare it in-parallel with other published or in-house methods to identify the most rapid, efficient, and consistent procedure for foodborne virus isolation and detection.

FDA Commissioner's Fellowship Program

2015 Preceptors



Jane Bai, Ph.D.

Center for Drug Evaluation and Research (CDER)

Silver Spring, MD 20993

Background:

Ph.D. Pharmaceutics

Master degree in Applied mathematics

BS: Pharmacy

FDA employment: August, 2005-present

Research Interests:

1. Constructing the knowledge and database for known biological and chemical threats,
2. Systems pharmacology approaches to mapping the biological pathways/networks perturbed by biological and chemical threats,



Alex M. Bailey, Ph.D.

Team Lead, Pharmacology/Toxicology Branch
(PTB)

Division of Clinical Evaluation and Pharmacology/
Toxicology (DCEPT)

Office of Cellular, Tissue, and Gene Therapies
(OCTGT)

Center for Biologics Evaluation and Research
(CBER)

US FDA

10903 New Hampshire Avenue

Silver Spring, MD 20993

FDA / CBER / OCTGT

Background:

- B.S. (Mechanical Engineering), Tufts University
- Ph.D. (Biomedical Engineering), University of Virginia

At the US FDA since 2010



Frederick A. Beland, Ph.D.

Division of Biochemical Toxicology
National Center for Toxicological Research
Jefferson, AR 72079

Background:

B.A., Colorado College

M.S., Montana State University

Ph.D., Montana State University

FDA Experience - 37 years

Research Interests:

Molecular toxicology, molecular carcinogenesis, genetics, and epigenetics.

Jonathan R. Deeds, Ph.D., M.Sc.



Method Development Branch

Division of Analytical Chemistry

Office of Regulatory Science

FDA Center for Food Safety and Applied Nutrition

College Park, MD

Background

Ph.D. Marine, Estuarine, and Environmental Science, University of Maryland, 2003

M.Sc. Environmental Toxicology, University of Louisiana at Lafayette, 1997

B.S. Biology, University of Dayton, 1995

Research Interests:

Seafood is a highly valued, globally traded commodity. Seafood is unique among the animal products regulated by the FDA in that several thousand species are harvested and distributed globally, with each species having distinct qualities, availabilities, and, in some cases, associated hazards. These qualities, values, and hazards can sometimes differ for the same species based on factors such as where it was harvested and whether it is wild caught or farmed. Proper labeling of seafood is critical to FDA's regulatory mission in terms of protecting U.S. consumers from seafood associated hazards and from protecting consumers from economically motivated fraud. Reliable analytical methods for species identification are essential to FDA's responsibility to enforce the accurate labeling of seafood. In the early 1990's, in response to numerous inquiries regarding labeling and substitution issues, the Agency started a formal program in seafood product identification. For products that could not be identified visually, the analytical method used at that time was based on isoelectric focusing of proteins or "IEF." Around 2005, FDA first began to explore the use of DNA to identify seafood products as a replacement for the now outdated IEF method which is less specific and more subject to changes due to processing and cooking. By the end of 2011, FDA had validated and published a DNA based method for identification of seafood and by 2012 nine FDA regional field laboratories had been equipped, trained, and proficiency tested for DNA testing of seafood, beginning its routine use at FDA. In addition, interagency agreements and contracts were established with seafood taxonomists to build a Federal DNA Reference Standard Seafood Library containing standard DNA sequences that link to reference specimens housed permanently in museum collections such as the Smithsonian National Museum of Natural History in Washington, D.C.

Aref El-Demerdash, Ph.D.



Kansas City Laboratory

Southwest Region

Office of Regulatory Affairs

U. S. Food and Drug Administration

11510 W. 80th Street

Lenexa, KS 66214 and

B

Background:

6 years of FDA employment

Ph. D. Environmental toxicology

Research Interests:

Developing methods/fast screening methods to detect API's in dietary supplements; developing mass spectrometry based methods to characterize drug substances or drug products.



Steven Foley, PhD

Division of Microbiology
National Center for Toxicological Research
Jefferson, AR 72079

Background:

B.S. in Zoology, North Dakota State University, Fargo, ND

Ph.D. in Cellular and Molecular Biology/Infectious Diseases, North Dakota State University, Fargo, ND

FDA Experience: 12 years

Research Interests:

My research interests are largely in the fields of bacterial pathogenesis, zoonoses, food safety, and molecular methods for pathogen characterization. Specific areas of interest include understanding the distribution of enteric pathogens, and their virulence and antimicrobial resistance factors in food production environments. By understanding the distribution mechanisms of pathogens, we may be able to develop interventions to reduce the spread of pathogenic microorganisms from food sources to humans. I am also interested in the development of methods to better understand the contribution of plasmid encoded genes to enhanced bacterial function. Plasmids are capable of horizontal gene transfer, which could facilitate the spread of antimicrobial resistance and increased virulence among bacteria leading to more difficult to treat infections. Thus a more comprehensive understanding of plasmid genetics and associated physiology should ultimately lead to improved public health.



Eric A.E. Garber, Ph.D.

Division of Bioanalytical Chemistry, Office of Regulatory Science, Center for Food Safety and Applied Nutrition (CFSAN).

Lab Address: CFSAN, HFS-716,
5100 Paint Branch Pkwy.,
College Park, MD 20740

Background:

Ph.D. Biochemistry, Brandeis Univ. 1983

B.S. Biochemistry, CCNY 1978

Employment

2002 – present, FDA

Research Interests:

Application of protein specific diagnostics to the detection and characterization of food as it relates to safeguarding consumers.



Denise Gavin, Ph.D.

Gene therapy Branch, Division of Cell and Gene Therapy

10903 New Hampshire Ave

WO 71-5328

Silver Spring, MD

Background:

Dr. Gavin is the Acting Gene Therapy Branch Chief. She has been with the FDA for 13 years. She has been in GTB for 13 yrs.

Research Interests:

Cancer immunotherapy, cell and gene therapies, product manufacturing and testing



Dionna J. Green, M.D.

Medical Officer
Pediatric Clinical Pharmacology Staff
Office of Clinical Pharmacology
Office of Translational Sciences
CDER

Background:

B.S. in Biology, 2001; M.D., 2005

Pediatric Residency, 2008

Clinical Pharmacology Fellowship, 2009

FDA Commissioner's Fellowship Program, 2009-2011

Biohazardous Threat Agents and Emerging Infectious Diseases 2-Yr Certificate Program, 2011-2013

Total years of FDA employment, 6 years

Research Interests:

Neonatal and pediatric drug development, trial methodology, pharmacogenomics, medical countermeasure development.



Stephanie L. Healey, M.S.

Winchester Engineering and Analytical Center,
ORA

Winchester, MA

Background:

Supervisory Chemist

B.S. Geological Sciences

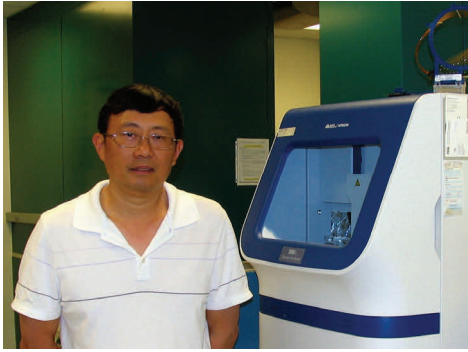
M.S. Geochemistry

6 years total experience with FDA

5 years employment with FDA

1 year research experience with FDA as contractor

Research Interests: Method Development in the detection of radioactive contamination of food products and packaging.



Yuan Hu, M.D.

Northeast Regional Laboratory/ORA/FDA

158-15 Liberty Ave.

Jamaica, NY 11433

Background:

1983 M.D. Guangzhou Medical University

1990 M.S. St. John's University

1991-1999 Research Scientist, Albert Einstein

Medical College, Bronx Lebanon Hospital Center

1999-Present FDA, Research Microbiologist (Virologist)

New York State licensed clinical laboratory director

Research Interests:

1. Isolation and extraction of foodborne viruses from food samples
2. Nested real-time PCR for the detection of foodborne viruses
3. Whole Genome sequencing analysis of foodborne viruses
4. Discovery of unrecognized and uncharacterized viral agents
5. Hepatitis C virus spontaneous mutations in continuous cell lines



James M. Hungerford, Ph.D.

Applied Technology Center, PRL-NW, ORA
22201 23rd Dr SE, Bothell, WA

Background:

Ph.D., University of Washington, Seattle, WA (Analytical Chemistry)

BS, MS, Western Washington University, Bellingham, WA (Organic)

My studies in graduate school and post-doc dealt with rapid tests and automated analytical chemistry (microfluidics and FIA work for Ph.D.) and in my MS work I was studying organic and organometallic synthesis. I have worked for FDA since 1987 as a research chemist

Research Interests:

Rapid tests for onsite testing of seafoods, cytotoxicity assays for ciguatoxins in fish, detection of histamine in fish, algal shellfish toxins by HPLC and cell assay, automation of chemical methods (FIA)



Aric D. Kaiser, M.S.

Expert Biomedical Engineer
US Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Division of Orthopaedic Devices

Background:

B.S., Biomedical Engineering, Case Western Reserve University, 1985

M.S., Mechanical Engineering, University of Cincinnati, 1987

FDA experience – since 1994

Research Interests:

Aric Kaiser, an expert biomedical engineer with experience in tissue mechanics and mechanical testing, has regulatory and scientific interests in the design and evaluation of products intended to treat orthopedic disorders. Of particular interest are tissue-engineered medical products (combination products) and devices intended to serve as functional replacements for the diseased or damaged tissue, *e.g.*, products intended to repair/regrow damaged cartilage with functional tissue rather than implantation of synthetic materials as in total joint replacements. Recent work has focused on bone void fillers containing calcium salts, collagen and/or recombinant human proteins or synthetic peptides.



Allison Kumar, Ph.D.

Center for Devices and Radiological Health
Silver Spring, MD

Background:

Harvard University - National Preparedness Leadership Institute

Georgetown University – Graduate Certificate, Biohazardous Threat Agents and Emerging Infectious Diseases

Virginia Tech – B.S. Engineering Science & Mechanics

Over 8 years at FDA

Research Interests:

Acute Trauma and Critical Care, Traumatic Brain Injury, Sepsis, Physiological Monitoring, Regulatory Strategy



Michael A. Pacanowski, M.P.H, Pharm.D.

Associate Director for Genomics and Targeted Therapy
Center for Drug Evaluation and Research
Office of Translational Sciences | Office of Clinical Pharmacology
10903 New Hampshire Avenue,
White Oak Building 51, Room 2132, HFD870
Silver Spring, MD 20993-0002
Office (301) 796-3919, Mobile (301) 529-4537

Background:

Pharm.D., Philadelphia College of Pharmacy, 2004
M.P.H. (Epidemiology), University of Florida, 2008
Clinical Pharmacology Residency, Bassett Healthcare, 2004-05
Pharmacogenomics Fellowship, University of Florida, 2005-08
Joined the FDA in 2008 (6 years)

Research Interests:

Pharmacogenomics, personalized medicine, clinical pharmacology, rare diseases



Anil K. Patri, Ph.D.

NCTR-ORA Nanotechnology Core Facility
Office of Scientific Coordination
National Center for Toxicological Research (NCTR)
FDA Jefferson Laboratories Campus
Jefferson, Arkansas 72079
870-543-7580; Anil.Patri@fda.hhs.gov

Background:

Ph.D.

5 months at FDA (August 2014-present)

Over 20 years experience in Nanotechnology with 10 years at the Frederick National Laboratory for Cancer Research on preclinical assessment of nanomedicines.

Research Interests:

All aspects of nanotechnology regulatory research in medical products from synthesis of nanomaterial based drugs, imaging agents and devices, material characterization, in vitro biocompatibility and in vivo safety and efficacy assessment.



Keith Peden, Ph.D.

Chief, Laboratory of DNA Viruses

Division of Viral Products

Center for Biologics Evaluation and Research (CBER)

Silver Spring, MD

Background:

Ph.D. degree

Twenty-one years at CBER/FDA

Research Interests:

Investigating the mechanism of oncogenic transformation by DNA tumor viruses; establishing *in vivo* assays to detect and quantify the oncogenic activity of cellular DNA; developing *in vitro* assays that quantify the reduction in the biological activity of DNA; understanding the relationship between the mechanism by which a cell becomes tumorigenic and the safety of biologics manufactured in tumorigenic cells; determining the role of epigenetics in establishing a tumorigenic phenotype; developing neutralization assays that can be adapted to high throughput and that might facilitate the introduction of new vaccines by evaluating the host immune responses to the vaccines.



Igor P. Pogribny, M.D., Ph.D.

Division of Biochemical Toxicology
National Center for Toxicological Research

Background:

M.D., Ivano-Frankivsk Medical University

Ph.D., Kyiv National Medical University

FDA Experience, 16 years

Research Interests:

Molecular toxicology, molecular carcinogenesis, genetics, and epigenetics.

Irshad Sulaiman, M.Sc., M.Phil, Ph.D.



Microbiological Sciences Branch
Southeast Regional Laboratory (SRL)
Office of regulatory Affairs (ORA)

Background:

Ph.D. – University of Delhi, India

M.Phil. – A. M. University, India

M.Sc. – A. M. University, India

FDA Experience – 4 and half years (2008-Present)

Professional Experience:

2011-Present: Adjunct Professor, Department of Biology, Georgia State University, Atlanta, Georgia

2008-Present: Research Microbiologist, Southeast Regional Laboratory, FDA, Atlanta, Georgia

2003-2008: Research Scientist, Division of Scientific Resources, CDC, Atlanta, Georgia

1997-2003: Visiting Scientist, Division of Parasitic Diseases, CDC, Atlanta, Georgia

1996-1997: Research Fellow, Medical College of Georgia, Augusta, Georgia

1993-1996: Young Scientist, National Institute of Immunology, New Delhi

Research Interests:

Dr. Sulaiman joined the Microbiological Sciences Branch, Southeast Regional Laboratory, U. S. Food and Drug Administration, Atlanta, Georgia as a Research Microbiologist on October 12th of 2008, with over 16 years of research experience and expertise in the field of molecular genetics and its application in method development to detect and differentiate various human-pathogenic emerging infectious agents. Before coming to FDA, Dr. Sulaiman worked at the Centers for Disease Control (CDC) for eleven and half years from 1997 to 2008. Dr. Sulaiman obtained his PhD degree in 1992 to study Conservation Biology, Population Genetics and Ecology of Endangered Species from University of Delhi.

Dr. Sulaiman's research for over 20 years has focused on the molecular genetic characterization and rapid detection methods for human-pathogenic parasites (Cyclospora, Cryptosporidium, Giardia), bacteria (Cronobacter, Bacillus, Salmonella), viruses (orthopox, SARS, Hepatitis A), fungi (Microsporidia, Indicator fungal species from environmental swabs), and some pest species (the FDA "Dirty 22" species) responsible for the spreading of foodborne pathogens, from outbreak settings, routine surveillance and sporadic cases for their Detection, Prevalence, Epidemiology, Transmission Dynamics, Taxonomy, Phylogeny and Evolutionary Relationships of public health importance.

Dr. Sulaiman has published over 70 manuscripts in peer-reviewed journals with high impact factors, and written 4 book chapters in his area of expertise.



Fenhong Song, Ph.D.

Element Building
Office of Regulatory Science
Office of Regulatory Affairs
U. S. Food and Drug Administration
12420 Parklawn Drive
Rockville, MD 20857

Background:

Ph.D. Johns Hopkins University
6 years of FDA employment

Research Interests:

Developing methods/fast screening methods to detect API's in dietary supplements; developing mass spectrometry based methods to characterize drug substances or drug products.